The Regulations of Connecticut State Agencies are amended by adding section 22a-153-4, as follows:

(NEW)

Sec. 22a-153-4. Diagnostic x-rays and imaging systems in the healing arts.

(a) Definitions. For the purposes of this section:

(1) "Accessible surface" means the external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

(2) "Added filtration" means any filtration that is in addition to inherent filtration.

(3) "Aluminum equivalent" means the thickness of type 1100 aluminum alloy affording the same attenuation, under specified conditions, as the material in question.

(4) "Assembler" means any person engaged in the business of assembling, replacing or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services.

(5) "Attenuation block" means a block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy or other materials having equivalent attenuation.

(6) "Automatic exposure control" or "AEC" means a device, including a phototimer and an ion chamber, that automatically controls one or more technique factors in order to obtain a required quantity of radiation at a preselected location or locations.

(7) "Beam axis" means a line from the source through the centers of the x-ray fields.

(8) "Beam-limiting device" means a device that provides a means to restrict the dimensions of the x-ray field.

(9) "Bone densitometry system" means a medical device that uses electronically-produced ionizing radiation or radioactive material to determine the density of bone structures of human patients.

(10) "C-arm x-ray system" means an x-ray system in which the image receptor and x-ray tube housing assembly are connected by a common mechanical support system in order to maintain a desired spatial relationship. This system is designed to allow a change in the projection of the beam through the patient without a change in the position of the patient.

(11) "Cephalometric device" means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

(12) "Certified components" means components of x-ray systems that are subject to regulations promulgated under the federal Radiation Control for Health and Safety Act of 1968, Public Law 90-602.

(13) "Certified system" means any x-ray system that has one or more certified components.

(14) "Changeable filters" means any filter, exclusive of inherent filtration, that can be removed from the useful beam through any electronic, mechanical or physical process.

(15) "Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a set of observations, estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}} \left[\frac{\sum_{i=1}^{n} (x_i - \bar{x})^2}{n-1} \right]^{1/2}$$

where:

s = Standard deviation of the observed values;

$\bar{x}$ = Mean value of observations in sample;

x_i = i_{th} observation in sample;

n = Number of observations in sample.

(16) "Computed tomography" or "CT" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data.

(17) "Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons and other hardware necessary for manually setting the technique factors.

(18) "Cooling curve" means the graphical relationship between heat units stored and cooling time.

(19) "Dead-man switch" means a switch so constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

(20) "Dental position indicating device" or "PID" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source to skin surface distance. A PID may or may not incorporate or serve as a beam-limiting device.

(21) "Diagnostic imaging system" means an assemblage of components for the generation, emission, reception, transformation, storage and visual display of the resultant image.

(22) "Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

(23) "Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human for the purpose of diagnosis or visualization.

(24) "Diagnostic x-ray imaging system" means an assemblage of components for the generation, emission and reception of x-rays and the transformation, storage and visual display of the resultant x-ray image.

(25) "Direct scattered radiation" means scattered radiation that has been deviated in direction only by materials irradiated by the useful beam.

(26) "Entrance exposure rate" means the exposure free in air per unit time at a SID.

(27) "Field emission equipment" means equipment that uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

(28) "Filter" means material placed in the useful beam to preferentially absorb selected radiations.

(29) "Fluoroscopic imaging assembly" means a subsystem in which x-ray photons produce a visible image. It includes the image receptors such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

(30) "Focal spot (actual)" means the area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

(31) "General purpose radiographic x-ray system" means any radiographic x-ray system that, by design, is not limited to radiographic examination of specific anatomical regions.

(32) "Gonad shield" means a protective barrier for the testes or ovaries.

(33) "Half-value layer" or "HVL" means the thickness of specified material that attenuates the beam of radiation to an extent such that the exposure rate is reduced by one-half. In this definition, the contribution of all scattered radiation, other than any that might be present initially in the beam concerned is deemed to be excluded.

(34) "Healing arts screening" means the testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed radiographer legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

(35) "Heat unit" means a unit of energy equal to the product of the peak kilovoltage, milliamperes and exposure time in seconds, calculated as kVp x mA x second.

(36) "Image intensifier" means a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

(37) "Image receptor" means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form that can be made into a visible image by further transformations.

(39) "Inherent filtration" means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

(40) "Irradiation" means the exposure of matter to ionizing radiation.

(41) "kV" means kilovolts.

(42) "kWs" means kilowatt second.

(43) "Lead equivalent" means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

(44) "Leakage radiation" means radiation emanating from the diagnostic source assembly except for:

(1) The useful beam; and

(2) Radiation produced when the exposure switch or timer is not activated.

(45) "Leakage technique factors" means the technique factors that are used in measuring leakage radiation, are associated with the diagnostic source assembly and are defined as follows:

(1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs or the minimum obtainable from the unit, whichever is larger;

(2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and

(3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

(46) "Licensed radiographer" means a person holding a license issued pursuant to section 20-74bb of the Connecticut General Statutes.

(47) "Light field" means that area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

(48) "Line-voltage regulation" means the difference between the no-load and the load line potentials expressed as a percent of the load line potential, calculated using the following equation:

$$\text{Percent line-voltage regulation} = 100\ (V_n - V_l)/V_l$$

where:

V_n = No-load line potential; and
V_l = Load line potential.

(49) "mA" means milliampere.

(50) "mAs" means milliampere second.

(51) "Maximum line current" means the root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

(52) "Patient" means an individual or animal subjected to healing arts examination, diagnosis or treatment.

(53) "Peak tube potential," "kilovolts peak" or "kVp" means the maximum value of the potential difference across the x-ray tube during an exposure.

(54) "Phantom" means a volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. Both the atomic number (Z) and the density of "phantom" material are similar to that of tissue.

(55) "Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

(56) "Positive beam limitation" or "PBL" means the automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

(57) "Primary protective barrier" means the material, excluding filters, placed in the useful beam.

(58) "Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

(59) "Protective barrier" or "barrier" means a barrier of radiation absorbing material used to reduce radiation exposure, limited to either a primary or a secondary protective barrier:

(60) "Protective glove" means a glove made of radiation absorbing materials used to reduce radiation exposure.

(61) "Qualified expert" means an individual who has demonstrated to the satisfaction of the Commissioner that such individual possesses the knowledge, training and experience to measure ionizing radiation, to evaluate safety techniques and to give advice regarding radiation protection needs.

(62) "Radiation detector" or "detector" means a device that in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

(63) "Radiation therapy simulation system" means a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

(64) "Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern.

(65) "Radiographic imaging system" means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

(66) "Rating" means the operating limits as specified by the component manufacturer.

(67) "Recording" means producing a permanent form of an image resulting from x-ray photons.

(68) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction.

(69) "Secondary protective barrier" means the material that attenuates stray radiation.

(70) "Shutter" means a device, attached to the tube housing assembly, that can intercept the entire cross sectional area of the useful beam and that has a lead equivalency not less than that of the tube housing assembly.

(71) "Source" means the focal spot of the x-ray tube.

(72) "Source-image receptor distance" or "SID" means the distance from the source to the center of the input surface of the image receptor.

(73) "Spot-film" means a radiograph that is made during a fluoroscopic examination to record permanently conditions that exist during that fluoroscopic procedure.

(74) "Spot-film device" means a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor, including a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

(75) "SSD" means the distance between the source and the skin entrance plane of the patient.

(76) "Stray radiation" means the sum of leakage and scattered radiation.

(77) "Technique factors" means the following conditions of operation:

(1) For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs;

(2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;

(3) For CT x-ray systems designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in mA, x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width and the number of x-ray pulses in mAs;

(4) For CT x-ray systems not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

(78) "Termination of irradiation" means the stopping of irradiation in a fashion that will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

(79) "Tomogram" means the depiction of the x-ray attenuation properties of a section through the body.

(80) "Tube" means an x-ray tube, unless otherwise specified.

(81) "Tube housing assembly" means the tube housing with tube installed, including high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

(82) "Tube rating chart" means the set of curves that specify the rated limits of operation of the tube in terms of the technique factors.

(83) "Type 1100 aluminum alloy" means a material composed of 99.00 percent minimum aluminum and 0.12 percent copper.

(84) "Useful beam" means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the system to produce radiation.

(85) "Variable-aperture beam-limiting device" means a beam-limiting device that has capacity for stepless adjustment of the x-ray field size at a given SID.

(86) "Visible area" means that portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

(87) "X-ray exposure control" means a device, switch, button or other similar means by which an operator initiates or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

(88) "X-ray equipment," "equipment" or "stationary x-ray equipment" means an x-ray system, subsystem or component thereof, inclusive of the following types:

(1) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled;

(2) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried; and

(3) "Stationary x-ray equipment" means x-ray equipment installed in a fixed location.

(89) "X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

(90) "X-ray high-voltage generator" means a device that transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.

(91) "X-ray system" means an assemblage of components for the controlled production of x-rays. At a minimum, such a system includes an x-ray high-voltage generator, an x-ray control, a

tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components that function with the system are considered integral parts of the system.

(92) "X-ray table" means a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography and/or fluoroscopy including, but not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray , cassette tunnel, image intensifier or spot-film device beneath the tabletop.

(93) "X-ray tube" means any electron tube that is designed for the conversion of electrical energy into X-ray energy.

(b) General and administrative requirements for radiation safety.

Each registrant shall direct the operation of any x-ray system under the registrant's administrative control. The registrant or the registrant's agent shall assure the following:

(1) An x-ray system that does not meet the provisions of this section is not operated for diagnostic purposes;

(2) An individuals operating an x-ray system shall be adequately instructed in safe operating procedures and be competent in the safe use of the equipment as specified in Appendix A;

(3) A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel that specifies for all typical examinations performed with that system, a minimum of the following information:

(A) Patient's body part versus technique factors to be utilized;

(B) Except for dental intraoral radiography, the source to image receptor distance to be used; and

(C) Skin entrance exposure dose for a typical exam;

(4) Each registrant shall create and make available to x-ray operators written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system;

(5) Except for patients who cannot be moved out of the room, only the staff, ancillary personnel or other persons required for the medical procedure or training shall be in the room during a radiographic exposure. Other than the patient being examined:

(A) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material unless the medical needs of the patient dictate otherwise;

(B) The x-ray operator, other staff, ancillary personnel and other persons required for the medical procedure shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent material; and

(C) Human patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor;

(6) Except for cases in which shielding as required by this subdivision would interfere with the diagnostic procedure, shielding of not less than 0.5 mm lead equivalent material shall be used for human patients during radiographic procedures, including:

(A) Gonad shielding for patients who have not passed reproductive age, in which their gonads are in the direct beam; and

(B) Thyroid shielding for children and for adults in all plain cranial-facial imaging;

(7) Thyroid shielding shall be used on children and should be used on adults in all dentocranialfacial imaging where the use of such shielding does not interfere with the anatomic area being imaged;

(8) Individuals shall not be exposed to the useful beam except for healing arts purposes or if authorized by a licensed radiographer. Deliberate exposure for the following purposes is prohibited:

(A) Exposure of an individual for training, demonstration or other non-healing arts purposes, excluding human research subjects; and

(B) Exposure of an individual for the purpose of healing arts screening except as authorized by subsection (b)(11) of this section;

(9) For circumstances in which a patient or film must be provided with auxiliary support during a radiation exposure:

(A) Mechanical holding devices shall be used when the technique permits;

(B) Written safety procedures, as required by subsection (b)(4) of this section, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

(C) The human holder shall be instructed in personal radiation safety and protected as required by subsection (b)(5) of this section;

(D) Licensed operators shall not hold patients except in the case of emergencies;

(E) In those cases in which the patient must hold the film, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

(F) Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded;

(10) Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized, including the following:

(A) The speed of the screen and film combinations used shall be the fastest speed consistent with the diagnostic objective of the examinations. Film cassettes without intensifying screens shall not be used for any routine diagnostic radiological imaging with the exception of standard film packets for intraoral use in dental radiography;

(B) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality, with the exception of panoramic and cephalometric radiography for which the minimum film speed shall be rare earth or 400 speed;

(C) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray installation;

(D) An x-ray system subject to subsection (f) of this section shall not be utilized in procedures where the source to patient distance is less than 30 centimeters; and

(E) If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

(i) Be positioned properly with the tube side facing the right direction, and the grid centered to the central ray, and

(ii) If the grid is of the focused type, be of the proper focal distance for the SIDs being used;

(11) All individuals associated with the operation of an x-ray system are subject to the requirements of sections 22a-153-2(e)(1) through (e)(6), (e)(10), (e)(12) and (e)(13) of the Regulations of Connecticut State Agencies; and

(12) Each registrant shall maintain the following information for each x-ray system for inspection by the Commissioner:

(A) Model and serial numbers of all major components, and user's manuals for those components;

(B) Records of surveys, calibrations, maintenance and modifications performed on the x-ray system; and

(C) A copy of all correspondence with the Department regarding that x-ray system.

(c) X-ray film processing facilities and operations. Each registrant of an installation using a radiographic x-ray system and radiographic film shall have available the following equipment for handling and processing radiographic film:

(1) For processing of manually developed film:

(A) Processing tanks constructed of mechanically rigid, corrosion resistant material;

(B) The temperature of solutions in the tanks maintained within the range of 60^{o} F to 80^{o} F (16^{o} C to 27^{o} C). Except as provided in subsection (g)(3)(F) of this section, film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the time-temperature relationships of Table 4-1; and

Table 4-1. Time-temperature chart for manual radiographic film developing.

Thermometer Reading (Degrees)		Minimum Developing Time (Minutes)
^{o}C	^{o}F	
26.7	80	2
26.1	79	2
25.6	78	2.5
25.0	77	2.5
24.4	76	3
23.9	75	3

23.3	74	3.5
22.8	73	3.5
22.2	72	4
21.7	71	4
21.1	70	4.5
20.6	69	4.5
20.0	68	5
19.4	67	5.5
18.9	66	5.5
18.3	65	6
17.8	64	6.5
17.2	63	7
16.7	62	8
16.1	61	8.5
15.6	60	9.5

(C) Devices that will indicate the actual temperature of the developer and signal the passage of a preset time appropriate to the developing time required;

(2) For processing with automatic processors and other closed processing systems:

(A) Except as provided in subsection (g)(3)(F) of this section, films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the time-temperature relationships of Table 4-2; and

Table 4-2. Time-temperature relationships for automatic processing of radiographic film.

Developer Temperature		Minimum Immersion Time[a/]
^{o}C	^{o}F	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29

29.5	85	30
[a/] Immersion time only, no crossover time included.		

(B) The specified developer temperature and immersion time shall be posted in the darkroom or on the automatic processor;

(3) Additional equipment and storage requirements:

(A) Pass boxes, if provided, shall be constructed to exclude light from the darkroom when cassettes are placed in or removed from the boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film;

(B) The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from one to two when processed shall not suffer an increase in density greater than 0.1 or 0.05 for mammography when exposed in the darkroom for two (2) minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film;

(C) Darkrooms used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed;

(D) Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container;

(E) Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to achieve radiographs of good diagnostic quality;

(F) Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with the manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed; and

(G) Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer; and

(4) Any processing deviations from subsections (c)(1) and (c)(2) of this section shall be recorded by the registrant in such manner that the requirements are shown to be met or exceeded

(d) General requirements for diagnostic x-ray systems. Any registrant using a diagnostic x-ray system shall operate such system in accordance with the following requirements:

(1) The control panel containing the main power switch shall bear the following warning statement, legible and accessible to view:

"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(2) On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation;

(3) The leakage radiation from the diagnostic source assembly measured at a distance of one meter in any direction from the source shall not exceed 25.8 μC/kg (100 milliroentgens) in one hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters (100 cm^2) with no linear dimension greater than twenty (20) centimeters;

(4) Radiation from components other than the diagnostic source assembly. The radiation emitted by a component other than the diagnostic source assembly shall not exceed 0.5 μC/kg (2 milliroentgens) in one hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters (100 cm^2) with no linear dimension greater than twenty (20) centimeters;

(5) Beam quality.

(A) Half-value layer.

(i) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table 4.3. If it is necessary to determine such half-value layer at an x-ray tube potential that is not listed in Table 4.3, linear interpolation or extrapolation may be made,

TABLE 4.3. Half-value layers.

Design Operating Range	Measured Potential (kVp)	Half-Value Layer In mm Aluminum	
		Dental Intra-oral Manufactured Before Aug. 1, 1974 and on or after Dec. 1, 1980	All Other Diagnostic X-Ray Systems
Below 51	30	N/A	0.3
	40	N/A	0.4
	50	1.5	0.5
51 to 70	51	1.5	1.2
	60	1.5	1.3
	70	1.5	1.5

Above 70	71	2.1	2.1
	80	2.3	2.3
	90	2.5	2.5
	100	2.7	2.7
	110	3.0	3.0
	120	3.2	3.2
	130	3.5	3.5
	140	3.8	3.8
	150	4.1	4.1

(ii) For capacitor energy storage equipment, compliance with the requirements of subsection (d)(5)(A) of this section shall be determined with the system fully charged and a setting of 10 mAs for each exposure, and

(iii) The required minimal half-value layer of the useful beam shall include the filtration contributed by all materials that are permanently between the source and the patient; and

(B) Filtration controls. For x-ray systems that have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with any filters and shall prevent an exposure unless the minimum amount of filtration necessary to produce the HVL required by subsection (d)(5)(A) of this section is in the useful beam for the given kVp that has been selected;

(6) For equipment installed after the effective date of this section, where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes that have been selected shall be indicated clearly prior to initiation of the exposure. Such indication shall be both on the x-ray control panel and at or near the tube housing assembly that has been selected;

(7) The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system;

(8) Technique indicators.

(A) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors set prior to the exposure shall be indicated; and

(B) The requirement of subparagraph (A) of this subdivision may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by a fluoroscopist;

(9) Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the 21 CFR 1020 shall be maintained in compliance with applicable requirements of that certification; and

(10) All position locking, holding and centering devices on x-ray system components and systems shall function as intended.

(e) Fluoroscopic x-ray systems. Any registrant using a fluoroscopic x-ray system shall operate such system in accordance with the following requirements:

(1) Each registrant shall limit the useful beam as follows:

(A) Primary barrier.

(i) Provide the fluoroscopic imaging assembly with a primary protective barrier that intercepts the entire cross section of the useful beam at any SID, and

(ii) Ensure that the x-ray tube used for fluoroscopy does not produce x rays unless the barrier is in position to intercept the entire useful beam;

(B) Fluoroscopic beam limitation.

(i) For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent (4%) of the SID,

(ii) For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutters fully opened during fluoroscopy or spot filming shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than twenty (20) centimeters table top to the film plane distance,

(iii) For uncertified fluoroscopic systems without a spot film device, the requirements of subsection (e)(1)(B)(i) of this section apply,

(iv) Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field,

(v) All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided with either stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less,

(vi) If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size five centimeters (5 cm) by five centimeters (5 cm) or less,

(vii) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and

(viii) For non-circular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field that pass through the center of the visible area of the image receptor;

(C) Spot-film beam limitation. A registrant using a spot-film device shall meet the following requirements:

(i) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film that has been selected on the spot film selector. Such adjustment shall be automatic, except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For a spot film device manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option,

(ii) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent (3%) of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent (4%) of the SID,

(iii) Allow for adjustment of the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five centimeters (5 cm) by five centimeters (5 cm),

(iv) The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent (2%) of the SID, and

(v) On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is

perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor;

(D) If a means exists to override any of the automatic x-ray field size adjustments required in subsections (e)(1)(B) and (C) of this section, such means shall:

(i) Be designed for use only in the event of system failure,

(ii) Incorporate a signal visible at the fluoroscopist's position that will indicate whenever the automatic field size adjustment is overridden, and

(iii) Be clearly and durably labeled as follows:

FOR X-RAY FIELD
LIMITATION SYSTEM FAILURE

(2) Activation of the fluoroscopic tube. Each registrant shall control X-ray production in the fluoroscopic mode by a device that requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure at any time, but means may be provided to permit completion of any single exposure of the series in process.

(3) Each registrant shall limit the exposure rate as follows:

(A) Entrance exposure rate allowable limits.

(i) Fluoroscopic equipment that is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(a) During recording of fluoroscopic images, or

(b) When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed,

(ii) Fluoroscopic equipment that is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current that will result in a exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, except:

(a) During recording of fluoroscopic images, or

(b) When an optional high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed,

(iii) Fluoroscopic equipment that is provided with both automatic exposure and a manual mode shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of 2.6 mC/kg (10 roentgens) per minute in either mode at the point where the center of the useful beam enters the patient, except in the following circumstances:

(a) During recording of fluoroscopic images, or

(b) When the mode or modes have an optional high level control, in which case that mode or modes shall not be operable at any combination of tube potential and current that results in an exposure rate in excess of 1.3 mC/kg (5 roentgens) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed,

(iv) Any fluoroscopic equipment manufactured after May 19, 1995 that can exceed 1.3 mC/kg (5 roentgens) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be 2.6 mC/kg (10 roentgens) per minute with an upper limit of 5.2 mC/kg (20 roentgens) per minute when high level control is activated,

(v) Compliance with the requirements of subsection (e)(3) of this section shall be determined as follows:

(a) If the source is below the x-ray table, the exposure rate shall be measured one centimeter (1 cm) above the tabletop or cradle,

(b) If the source is above the x-ray table, the exposure rate shall be measured at thirty centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement,

(c) For a C-arm type of fluoroscope, the exposure rate shall be measured thirty centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than thirty centimeters from the input surface of the fluoroscopic imaging assembly,

(d) For a lateral type fluoroscope, the exposure rate shall be measured at a point fifteen centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. A movable tabletop shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than fifteen centimeters to the centerline of the x-ray table; and

(B) Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both typical and maximum values by placing materials in the useful beam and taking the following actions:

(i) Such measurements shall be made annually or after any maintenance of the system that might affect the exposure rate,

(ii) Results of these measurements shall be posted where any fluoroscopist may have ready access to such results while using the fluoroscope and in the record required in subsection (b)(12)(C) of this section. The measurement results shall be stated in coulombs per kilogram (roentgens) per minute and include the technique factors used in determining such results. The name of the individual performing the measurements and the date the measurements were performed shall be included in the results,

(iii) Conditions of periodic measurement of typical entrance exposure rate are as follows:

(a) The measurement shall be made under the conditions that satisfy the requirements of subsection (e)(3)(A)(v) of this section,

(b) The kVp, mA and other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient, and

(c) The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions of subparagraph (B)(iii)(b) of this subdivision, and

(iv) Conditions of periodic measurement of maximum entrance exposure rate are as follows:

(a) The measurement shall be made under the conditions that satisfy the requirements of subsection (e)(3)(A)(v) of this section,

(b) The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate, and

(c) The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

(4) Each registrant shall limit the barrier transmitted radiation rate as follows:

(A) The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed 0.5 μC/kg (2 milliroentgens) per hour at ten centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each mC/kg (roentgen) per minute of entrance exposure rate; and

(B) Measuring compliance of barrier transmission.

(i) The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of one hundred square centimeters (100 cm^2) with no linear dimension greater than twenty centimeters,

(ii) If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty centimeters above the tabletop,

(iii) If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than thirty centimeters, and

(iv) Movable grids and compression devices shall be removed from the useful beam during the measurement.

(5) During fluoroscopy and cinefluorography, each registrant shall provide for the kV and the mA to be indicated continuously.

(6) Each registrant shall use SSDs not less than:

(A) Thirty-eight centimeters on stationary fluoroscopic systems manufactured on or after August 1, 1974;

(B) Thirty-five and one-half centimeters on stationary fluoroscopic systems manufactured prior to August 1, 1974;

(C) Thirty centimeters on all mobile fluoroscopes; or

(D) Twenty centimeters for all mobile fluoroscopes when used for specific surgical applications.

(7) Each registrant shall provide means to preset the cumulative on-time of the fluoroscopic x-ray tube as follows:

(A) The maximum cumulative time of the timing device shall not exceed five minutes without resetting; and

(B) A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.

(8) Each registrant shall control scattered radiation as follows:

(A) Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to unattenuated scattered radiation that originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent;

(B) Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the unattenuated scattered radiation emanating from above the tabletop unless that individual:

(i) Is at least 120 centimeters from the center of the useful beam, or

(ii) The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover

panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in subsection (b)(5) of this section; and

(C) The Commissioner may grant exemptions to subsection (e)(8)(B) of this section where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Commissioner shall not permit such exemption.

(9) For fluoroscopic systems equipped with spot film mode, each registrant shall meet the exposure reproducibility requirements of subsection (f) of this section when operating in the spot film mode.

(10) Radiation therapy simulation systems. Each registrant operating a radiation therapy simulation system shall be exempt from all the requirements of subsection (e)(3) of this section. A registrant operating such a system shall be exempt from:

(A) The requirements of subsections (e)(1) and (e)(4) of this section provided such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and

(B) The requirements of subsection (e)(7) of this section if such systems are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.

(11) Operator qualification. Each registrant shall allow only a licensed radiographer who is trained in the safe use of fluoroscopic x-ray systems to operate such systems.

(12) Each registrant shall operate flouroscopic x-ray equipment as follows:

(A) All imaging formed by the use of fluoroscopic x-ray systems shall be viewed, directly or indirectly, and interpreted by a licensed radiographer; .

(B) The use of fluoroscopic x-ray systems by radiologic technologists shall be performed under the supervision of a licensed radiographer for the purpose of localization to obtain images for diagnostic purposes;

(C) Radiologic technology students shall not be allowed to operate fluoroscopic x-ray systems unless directly supervised by a licensed radiographer or radiologic technologist as specified in subdivision (11) of this subsection;

(D) Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations; and

(E) In a facility that uses a fluoroscopic x-ray system, maintain a record of the cumulative fluoroscopic exposure time used and the number of spot films for each examination. Such record shall indicate patient identification, type of examination, date of examination and operator's name.

(f) Radiographic systems other than fluoroscopic, dental intraoral, bone densitometry or computed tomography x-ray systems. Each registrant of a radiographic system that is not a fluoroscopic, dental intraoral, bone densitometry or computed tomography x-ray system shall operate such system in accordance with the requirements of this subsection.

(1) Each registrant shall limit the useful beam to the area of clinical interest. Evidence of compliance with this requirement shall include proper use of a positive beam limiting device that meets the manufacturer's specifications and the requirements of subsection (f)(8)(B) of this section or evidence of collimation on at least three sides or three corners of the film . Each registrant shall meet the following beam limitation requirements for each of the following radiographic systems

(A) For all general purpose stationary and mobile x-ray systems.

(i) Only x-ray systems provided with means for independent stepless adjustment of at least two dimensions of the x-ray field shall be used,

(ii) A method shall be provided for visually defining the perimeter of the x-ray field. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam, and

(iii) The Commissioner may grant an exemption on non-certified x-ray systems to subsection (f)(1)(A)(i) and (ii) of this section provided the registrant makes a written application for such exemption and in that application:

(a) Demonstrates it is impractical to comply with subsection (f)(1)(A)(i) and (ii) of this section, and

(b) Describes another method or methods used to address the requirements of subsection (f)(1)(A)(i) and (ii) of this section;

(B) For stationary general purpose x-ray systems. In addition to the requirements of subsection (f)(1)(A) of this section, a registrant of a stationary general purpose x-ray system, either certified or noncertified, shall meet the following requirements:

(i) Provide a method to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the

x-ray field with respect to the center of the image receptor to within two percent of the SID, and to indicate the SID to within two percent,

(ii) Use a beam-limiting device that indicates numerically the field size in the plane of the image receptor to which it is adjusted, and

(iii) Specify the field size dimensions and SIDs in inches or centimeters, and so that aperture adjustments result in x-ray field dimensions in the plane of the image receptor that correspond to those indicated by the beam-limiting device to within two percent of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor;

(C) For x-ray systems designed for one image receptor size at a fixed SID:

(i) Provide a means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or

(ii) Provide a means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor; and

(D) For x-ray systems other than those identified in subparagraphs (A), (B) and (C) of this subdivision:

(i) Provide a means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor,

(ii) Provide a means to align the center of the x-ray field with the center of the image receptor to within two percent of the SID, or to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor, and

(iii) For a system that meets the requirements for a general purpose x-ray system specified in subsection (f)(1)(A) of this section or for which alignment means are provided, a registrant may provide for the following as an alternative to compliance with subparagraphs (D)(i) and (D)(ii) of this subdivision:

(a) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image

receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed, or

(b) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

(2) Each registrant of a radiographic system shall control radiation exposure as follows:

(A) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. The operator shall not be able to initiate an exposure when the timer is set to a "zero" or "off" position, if either position is provided;

(B) Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced A signal audible to the operator shall indicate that the exposure has terminated;

(C) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero."

(i) An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for exposure:

(a) Of one-half second or less, or

(b) During serial radiography, when means shall be provided to permit completion of any single exposure of the series in process,

(ii) When an automatic exposure control is provided:

(a) Indication shall be made on the control panel when this mode of operation is selected,

(b) If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for

pulsed operation shall be equal to or less than a time interval equivalent to two pulses,

(c) The minimum exposure time for all equipment other than that specified in subsection (f)(2)(C)(ii)(b) of this section shall be equal to or less than one-sixtieth (1/60) second or a time interval required to deliver five mAs, whichever is greater,

(d) Either the product of peak x-ray tube potential, current and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure except that when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure, and

(e) A visible signal shall indicate when an exposure has been terminated at the limits required by subsection (f)(2)(C)(ii)(d) of this section, and manual resetting shall be required before further automatically timed exposures can be made;

(D) For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum, determined by the following equation:

$$(X_1 - X_2) \leq 0.1\,(X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values;

(E) The x-ray exposure control shall be so placed that the operator can view the patient while making any exposure; and

(F) Each registrant shall meet the following requirements for operator protection:

(i) For a stationary x-ray system, permanently mount the x-ray control in a protected area so that the operator is required to remain in that protected area during the entire exposure, and

(ii) For mobile and portable x-ray systems that are:

(a) Used continuously for greater than one week in the same location, meet the requirements of subsection (f)(2)(F)(i) of this section, and

(b) Used for less than one week at the same location, provide either a protective barrier at least two meters (6.5 feet) high for operator

protection during exposures, or means to allow the operator to be at least six feet from the tube housing assembly during the exposure.

(3) Each registrant shall provide a means to limit the source-to-skin distance on all mobile or portable radiographic systems to equal to or greater than thirty centimeters.

(4) When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, a registrant shall not exceed a coefficient of variation of exposure for both manual and automatic exposure control systems of 0.05. The requirement of this subdivision applies to clinically-used techniques.

(5) Each registrant shall limit radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated to a rate of 0.5 μC/kg (two milliroentgens) per hour at five centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

(6) Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent of the indicated value for kVp and twenty percent for time.

(7) For equipment operated at 40 to 100 percent of the maximum rated power supply specified by the manufacturer for any fixed x-ray tube potential, the registrant shall:

(A) For equipment having independent selection of x-ray tube current (mA), the average ratios (X_i) of exposure to the indicated milliampere-seconds product (C kg^{-1} mAs^{-1} (or mR/mAs)) obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum, calculated according to the following equation:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous;

(B) For equipment having a combined x-ray tube current exposure time product (mAs) selector, but not a separate tube current (mA) selector, the average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum, calculated according to the following equation:

$$X_1 - X_2 \leq 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two consecutive mAs selector settings, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection; and

(C) Determination of compliance shall be based on ten exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

(8) Each registrant of a diagnostic x-ray system incorporating one or more certified component shall be required to comply with the following additional requirements, as applicable to the certified component(s):

(A) For stationary and mobile general purpose x-ray systems, limit the beam as follows:

(i) Provide a means of stepless adjustment of the size of the x-ray field. The minimum field size at a SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters,

(ii) When a light localizer is used to define the x-ray field, such localizer shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement, and

(iii) The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination three millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination three millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring instrument aperture of one millimeter in diameter;

(B) If PBL is being used, the registrant shall meet the following requirements :

(i) PBL shall prevent the production of x-rays when:

(a) Either the length or width of the x-ray field in the plane of the image receptor differs, except as permitted by subsection (f)(8)(B)(iii) of this section, from the corresponding image receptor dimensions by more than three percent of the SID, or

(b) The sum of the length and width differences as stated in subsection (f)(8)(B)(i)(a) of this section without regard to sign exceeds four percent of the SID,

(ii) Compliance with subsection (f)(8)(B)(i) of this section shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five seconds after insertion of the image receptor,

(iii) The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum field size at a SID of 100 centimeters shall be equal to or less than five centimeters by five centimeters, and

(iv) The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function as described in subsection (f)(8)(B)(i) of this section, then any change of image receptor size or SID must cause the automatic return; and

(C) For beam limitation for portable x-ray systems, each registrant shall meet the beam limitation requirements of subsection (f)(1)(A) or (f)(1)(B) of this section.

(9) Each registrant shall use a tube stand or other mechanical support for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during exposures.

(g) Intraoral dental radiographic systems. Each registrant of x-ray equipment and associated facilities used for intraoral dental radiography shall operate such equipment and associated facilities in accordance with the requirements this subsection and subsections (b) and (d) of this section.

(1) Each registrant shall provide each X-ray system designed for use with an intraoral image receptor with means to limit SID to not less than 20 cm..

(2) No later than sixty (60) months from the effective date of this section, each registrant shall provide each radiographic system designed for use with an intraoral image receptor with rectangular collimation to limit the x-ray beam such that the beam at the minimum . SID shall be the approximate dimensions of the image receptor, accomplished by use of the position indicating device or accessory devices, except where anatomic constraints or the inability of the human subject to cooperate makes rectangular collimation and beam-film alignment impossible.

(3) Each registrant shall provide for the following radiation exposure controls:

(A) For exposure initiation:

(i) Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action, and

(ii) Exposure shall not be possible when the timer is set to a "zero" or "off" position, if either position is provided;

(B) For exposure indication, means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced, and a signal audible to the operator shall indicate that the exposure is occurring;

(C) For exposure termination:

(i) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses or a preset radiation exposure to the image receptor,

(ii) An x-ray exposure control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of 1/2 second or less, and

(iii) Termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "zero;"

(D) For systems having independent selection of exposure time settings, the average ratios (X_i) of exposure to the indicated timer setting, in units of C kg^{-1} s^{-1} (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum, determined using the following equation:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values;

(E) For exposure control location and operator protection,stationary x-ray systems shall have the x-ray exposure control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure;

(F) Dental radiographic films shall be developed according to the film manufacturers instructions for both the chemistry and time-temperature method; and

(G) For exposure control location and operator protection, mobile and portable x-ray systems that are:

(i) Used for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of subparagraph (E) of this subdivision, and

(ii) Used for less than one week in the same location shall be provided with either a protective barrier at least 6.5 feet high for operator protection, or means to allow the operator to be at least six feet from the tube housing assembly while making exposures.

(4) When the equipment is operated on an adequate power supply as specified by the manufacturer, each registrant shall limit the estimated coefficient of variation of radiation exposures to no greater than 0.05 for any specific combination of selected technique factors.

(5) For equipment operated on a power supply specified by the manufacturer for any fixed x-ray tube potential within the range of 40 percent to 100 percent of the maximum rated, each registrant shall provide for the following:

(A) For equipment having independent selection of x-ray tube current (mA), the average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive tube current settings shall not differ by more than 0.10 times their sum, calculated as follows:

$$X_1 - X_2 \leq 0.10 (X_1+X_2)$$

where X_1 and X_2 are the average values obtained at each of two consecutive tube current settings, or at two settings differing by no more than a factor of two where the tube current selection is continuous;

(B) For equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector, the average ratios (X_i) of exposure to the indicated milliampere-seconds product, in units of C kg^{-1} mAs^{-1} (or mR/mAs), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum, calculated as follows:

$$X_1 - X_2 \leq 0.10 (X_1 +X_2)$$

where X_1 and X_2 are the average values obtained at any two mAs selector settings, or at two settings differing by no more than a factor of 2 where the mAs selector provides continuous selection; and

(C) Determination of compliance shall be based on ten exposures taken within a time period of one hour, at each of the two settings. These two settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement,

focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

(6) For deviation of technique factors from indicated values for kVp and exposure time, if time is independently selectable, each registrant shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, each registrant shall not exceed a deviation of 10 percent of the indicated value for kVp and 20 percent for time.

(7) Each registrant of a dental x-ray machines with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

(8) Each registrant shall use the following administrative controls:

(A) Patient holding devices shall be used when clinically indicated;

(B) The tube housing and the PID shall not be hand-held during an exposure;

(C) The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of F.7b;

(D) Dental fluoroscopy without image intensification shall not be used; and

(E) The patient's name, type of examination(s), dates of examination(s), the reason for acquiring the images (selection criteria) and the finding on the images shall be recorded in the patient record.

(h) Computed tomography x-ray systems.

(1) For the purposes of this subsection, the following definitions apply:

"Computed tomography dose index" or "CTDI" means the integral from -7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan calculated according to the following equation:

$$CTDI = \frac{1}{n\,T} \int_{-7\,T}^{+7\,T} D(z)\,dz$$

where:

z	=	Position along a line perpendicular to the tomographic plane;
D(z)	=	Dose at position z;
T	=	Nominal tomographic section thickness;
n	=	Number of tomograms produced in a single scan.

The calculation of CTDI is based on the assumption that the dose profile is centered around z=0 and that for a multiple tomogram system the scan increment between adjacent scans is nT.

"Contrast scale" or "CS" means the change in the linear attenuation coefficient per CTN relative to water, calculated according to the following equation:

$$CS = \frac{\mu_x - \mu_x}{CTN_x - CTN_w}$$

where:

μ_x = Linear attenuation coefficient of the material of interest;
μ_w = Linear attenuation coefficient of water;
CTN_x = of the material of interest;
CTN_w = of water.

"CT conditions of operation" means all selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors defined in subsection (a) of this section.

"CT gantry" means the tube housing assemblies, beam-limiting devices, detectors and the supporting structures and frames which hold these components.

"CT Number" or "CTN" means the number used to represent the x-ray attenuation associated with each elemental area of the CT image, calculated according to the following equation:

$$CTN = \frac{k\,(\mu_x - \mu_w)}{\mu_w}$$

where:

k = A constant, a normal value of 1,000 when the Houndsfield scale of CTN is used;
μ_x = Linear attenuation coefficient of the material of interest;
μ_w = Linear attenuation coefficient of water.

"Dose profile" means the dose as a function of position along a line.

"Elemental area" means the smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted.

"Multiple tomogram system" means a computed tomography x-ray system that obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

"Noise" means the standard deviation of the fluctuations in CTN expressed as a percentage of the attenuation coefficient of water, estimated according to the following equation:

where:

$$S_n = \frac{s \bullet CS \bullet 100}{\mu_w}$$

S_n = Estimated value of noise.
CS = Linear attenuation coefficient of the material of interest.
μ_w = Linear attenuation coefficient of water.
s = Standard deviation of the CTN of picture elements in a specified area of the CT image.

"Nominal tomographic section thickness" means the full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

"Picture element" means an elemental area of a tomogram.

"Reference plane" means a plane that is displaced from and parallel to the tomographic plane.

"Scan" means the complete process of collecting x-ray transmission data for the production of one or more tomograms.

"Scan increment" means the amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

"Scan sequence" means a pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

"Scan time" means the period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

"Single tomogram system" means a CT x-ray system that obtains x-ray transmission data during a scan to produce a single tomogram.

"Tomographic plane" means that geometric plane that is identified as corresponding to the output tomogram.

"Tomographic section" means the volume of an object whose x-ray attenuation properties are imaged in a tomogram.

(2) Each registrant of a CT x-ray system shall meet the following equipment requirements:

(A) For termination of exposure:

(i) Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent of its preset value through the use of either a backup timer or devices that monitor equipment function,

(ii) A visible signal shall indicate when the x-ray exposure is in progress and has been terminated through the means required by subparagraph (A)(i) of this subdivision, and

(iii) The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration;

(B) For tomographic plane indication and alignment:

(i) For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane,

(ii) For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane may be offset from the location of the tomographic planes, and

(iii) If a device using a light source is used to satisfy the requirements subparagraphs (B)(i) or (B)(ii) of this subdivision, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions;

(C) For beam-on and shutter status indicators and control switches:

(i) The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed, and

(ii) Each emergency button or switch shall be clearly labeled as to its function;

(D) Each CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible;

(E) When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by subsection (d)(3) of this section;

(F) The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom; and

(G) For CT x-ray systems containing a gantry manufactured after September 3, 1985:

(i) The total error in the indicated location of the tomographic plane or reference plane shall not exceed five millimeters,

(ii) If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible,

(iii) The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel, and

(iv) Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

(2) Each registrant of a CT x-ray systems shall provide for the following in facility design:

(A) Two-way aural communication between the patient and the operator at the control panel; and

(B) Continuous observation of the patient during irradiation through windows, mirrors, closed-circuit television or an equivalent:

(i) Located so that the operator can observe the patient from the control panel, and

(ii) When the primary viewing system is electronic, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

(3) Each registrant shall have a survey made under the direction of a qualified expert as follows:

(A) For each of the following systems:

(i) Each CT x-ray system installed after the effective date of this section,

(ii) Each CT x-ray system not previously surveyed, and

(iii) Every CT x-ray system after any change in the facility or equipment that might cause a significant increase in radiation hazard; and

(B) The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the Commissioner upon request.

(4) Each registrant shall provide for calibration of the radiation output of each CT x-ray system as follows:

(A) Performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration;

(B) Performed at intervals specified by a qualified expert and after any change or replacement of components that, in the opinion of the qualified expert, may cause a change in the radiation output;

(C) Performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two years;

(D) CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

(i) CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode,

(ii) CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom.

Means for the placement of dosimeters or alignment devices at other locations may be provided,

(iii) Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom, and

(iv) All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present;

(E) Required for each type of head, body or whole-body scan performed at the facility;

(F) Performed as follows:

(i) The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness,

(ii) The CTDI along the two axes specified in subsection (h)(4)(D)(ii) of this section shall be measured. The manufacturer's statement as to the nominal tomographic section thickness for the system may be used to determine CTDI. The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant, and

(iii) The spot checks specified in subsection (h)(5) of this section shall be made; and

(G) Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Commissioner upon request.

(5) Each registrant shall use the following spot-check procedures on each CT x-ray system:

(A) All procedures shall be in writing and shall have been developed by a qualified expert;

(B) Procedures shall incorporate the use of a CT dosimetry phantom that has a capability of providing an indication of contrast scale, noise, nominal

tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material;

(C) All spot checks shall be included in the calibration required by subsection (h)(4) of this section and at time intervals and under system conditions specified by a qualified expert;

(D) Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations required by subsection (h)(4) of this section. Records of the images made shall be retained, until a new calibration is performed, as follows:

(i) Hard copies of the images obtained from the image display device, and

(ii) Stored in digital form on a storage medium compatible with the CT x-ray system; and

(E) Written records of the spot checks performed shall be maintained for inspection by the Commissioner.

(6) Each registrant shall operate each CT x-ray system as follows:

(A) Allow operation only by a licensed radiographer;

(B) Maintain readily available information regarding the operation and calibration of the system including:

(i) Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained,

(ii) Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters and the results of at least the most recent spot checks conducted on the system,

(iii) The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized, and

(iv) A current technique chart for adults and pediatrics available at the control panel that specifies for each routine examination the CT conditions of operation and the number of scans per examination; and

(C) If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert,

use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.

(i) Mammography certification requirements are as follows:

(1) Only x-ray systems, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900, shall be used to screen and diagnose with mammography;

(2) The owner or operator of a facility performing mammography shall have a valid certificate issued by the U.S. Department of Health and Human Services, pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900; and

(3) The owner or operator of a facility performing mammography shall ensure that the additional mammography activities of processing the x-ray film, interpreting the image and maintaining viewing conditions, wherever performed, meet all quality standards pursuant to the Mammography Quality Standards Reauthorization Act of 1998, Public Law 105-248, and 21 C.F.R. Part 900.

Statement of purpose: This section establishes requirements on a registrant for the use of diagnostic x-ray equipment and imaging systems by, or under the supervision of, an individual authorized by and registered in accordance with the Connecticut General Statutes to engage in medical or dental medicine.

APPENDIX A

DETERMINATION OF COMPETENCE

The following are areas in which the agency considers it important that an individual have expertise for the competent operation of x-ray equipment:

(a) Familiarization with equipment
- (1) Identification of controls
- (2) Function of each control
- (3) How to use a technique chart

(b) Radiation Protection
- (1) Collimation
- (2) Filtration

(3) Gonad shielding and other patient protection devices if used
(4) Restriction of x-ray tube radiation to the image receptor
(5) Personnel protection
(6) Grids

(c) Film Processing
(1) Film speed as related to patient exposure
(2) Film processing parameters
(3) Quality assurance program

(d) Emergency Procedures
(1) Termination of exposure in event of automatic timing device failure

(e) Proper Use of Personnel Dosimetry, if Required

(f) Understanding Units of Radiation